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Design aspects of compliant, soft layer bearings for an experimental hip prosthesis

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Abstract: Currently, an artificial hip joint can be expected to last, on average, in excess of 15 years with failure due, in the majority of cases, to late aseptic loosening of the acetabular component. A realistic alternative to the problem of wear in conventional joints is the introduction of bearing surfaces that exhibit low wear and operate in the full fluid-film lubrication regime. Contact analyses and friction tests were performed on compliant layer joints (metal-on-polyurethane) and the design of a prototype ovine arthroplasty model was investigated. When optimized, these components have been shown to achieve full fluid-film lubrication.

Keywords: total hip replacement, polyurethane, friction

1 INTRODUCTION

The healthy natural synovial joint provides low wear and low friction for many decades. It operates in the full fluid-film lubrication regime for much of the time [1, 2], which is achieved by a combination of elastohydrodynamic lubrication (EHL), microelastohydrodynamic lubrication (μ EHL) and squeeze-film lubrication. Unfortunately, diseases such as osteoarthritis or injury can destroy this natural bearing system. The pain, discomfort, and disability caused by diseased or damaged joints can be alleviated by joint arthroplasty.

Present successful designs of artificial hip joints largely owe their success to Professor Sir John Charnley who introduced the metal femoral head articulating against an ultra-high molecular weight polyethylene (UHMWPE) acetabular component. However, currently a hip prosthesis can be expected to last, on average, in excess of 15 years with failure due, in the majority of cases, to late aseptic loosening of the acetabular component [3, 4]. This failure is due to the fact that conventional artificial joints

operate in the mixed lubrication regime, where the bearing surfaces are not completely separated and the load is carried partly by the fluid pressure and partly by the contacting asperities [5–8]. This contact inevitably results in wear. Wear debris leads to bone resorption and eventually to late aseptic loosening [9].

A solution to the problem of wear in conventional metal or ceramic on UHMWPE prostheses is the introduction of bearing surfaces that exhibit low wear and operate in the full fluid-film lubrication regime. Hard-on-hard bearing surfaces (such as metal-on-metal or ceramic-on-ceramic) produce lower wear rates than conventional joints, largely because of their hardness, but also because, under some conditions, they can produce predominantly fluid-film lubrication [7, 10]. However, while this approach has demonstrated its merits in terms of reducing wear debris, only one system aims to restore the lubrication regime to that of the natural joint and therefore further reduce the wear. This is the use of compliant layer joints [11, 12]. Compliant layer joints are designed to operate in a similar way to the healthy natural synovial joint in that they incorporate a 'compliant', hydrophilic polyurethane layer rather than polyethylene as the acetabular cup bearing surface, thus promoting the joint to enjoy full fluid-film lubrication using both EHL and μ EHL.

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Table 1 Chemical structures of candidate polyurethanes

Trade name	Soft segment	Hard segment	Chain extender	Reference
Estane 57, 58*	Not published	Not published	Not published	21
Corethane†	HMEC	MDI	BD	22
Pellethane‡	PTMEG	MDI	BD	23
Tecoflex 85A-100A§	PTMEG	HMDI	BD	24

* Supplied by B. F. Goodrich, Cleveland, Ohio.
† Developed by Corvita Corp., Miami, Florida, now supplied by Polymer Technology Group, Irvine, California, under Bionate®.
‡ Supplied by Dow Chemical, La Porte, Texas.
§ Supplied by Thermedics, Inc., Woburn, Massachusetts.

This study evaluates the friction and lubrication regimes of compliant layer joints (novel metal-on-polyurethane) and considers the design of the prototype ovine arthroplasty model for the pre-clinical trial of these prostheses.

2 MATERIALS

Healthy cartilage within the natural synovial joint has a thickness that has been measured at 2–4 mm on both the femoral head and acetabular cup [13, 14]. The modulus of elasticity is 10–50 MPa [15] with a Poisson’s ratio of 0.42–0.47 in unconfined compression [16]. The surface roughness (R_a) of healthy cartilage is about 2.0 μm [17], but it is higher for diseased joints [18]. This increase in surface roughness, along with the cartilage becoming softer and thinner [19, 20], affects the lubrication mechanisms and wear of natural joints. Therefore, in an attempt to design a prosthesis that will operate under similar lubrication mechanisms as healthy natural joints, but using synovial fluid produced in rheumatoid joints (i.e. low viscosity), compliant layer joints have been introduced [11].

The compliant layer joints were metal-on-polyurethane (PU) joints. The polyurethanes under investigation covered a range of material hardness values (Shore hardnesses of 80A-100A) and were Pellethane 2363, Estane, Tecoflex, and Corethane. The chemical structures of these biomaterials are listed in Table 1. The measured hardness values (on

the DIN scale) of the polyurethane layers are shown in Table 2. The effects of layer thickness on the interface shear stresses between the elastomeric layer and a rigid backing, the contact area, and the surface deflections under load were assessed by Strozzi and Unsworth [25]. Layer thicknesses of 0.5–3 mm were examined numerically, the best thickness being found to be 2 mm. Therefore, these layers were designed to be 2 mm thick. The surface roughnesses (R_a) were about 2.0 μm , which is similar to healthy cartilage. The femoral components of the human test prostheses were 15.88 mm in radius and were stainless steel for most of the joints. However, the Corethane acetabular cups were matched against a CoCrMo femoral head of 15.96 mm in radius.

3 EXPERIMENTAL METHODS

Contact analyses and Stribeck plots were evaluated for the compliant layer joints. An ovine arthroplasty model was also designed for use in the pre-clinical trials [26].

3.1 Contact area analysis

The transmission of applied forces between two surfaces (i.e. the femoral head and acetabular cup) takes place across a finite area. The size of the contact radius, which is dependent on the elastic deformation of the surfaces, determines the pressures that will be generated at the interface under a given applied load. Tribological theory predicts that the lubricating film is more easily generated if the pressures are kept low. Therefore, it is preferable to have as large a contact radius as possible, consistent with keeping the interface stress within a safe region [27].

Hertzian contact theory can be applied to the conventional UHMWPE joints to assess the contact radii of these joints. Although Hertzian theory refers to a spherical indenter on a flat surface, the ball-in-cup arrangement can be investigated with a model based

Table 2 Hardness measurements of the polyurethane layers (DIN scale)

Polyurethane	Hardness (N/mm ²)
Estane 57	4.8
Estane 58	5.2
Corethane	5.4
Pellethane	5.2
Tecoflex 85A	3.8
Tecoflex 93A	6.0
Tecoflex 100A	9–10

on the equivalent radius

$$\frac{1}{R_x} = \frac{1}{R_h} - \frac{1}{R_c} \quad (1)$$

where R_x is the equivalent radius, R_h is the radius of the femoral head, and R_c is the radius of the acetabular cup. The equivalent radius can be used to assess the radius of the contact circle

$$a = \left(\frac{3LR_x}{2E'} \right)^{1/3} \quad (2)$$

where a is the contact radius, L is the applied load (2000 N), and E' is the equivalent elastic modulus of the material pairing. The equivalent elastic modulus is defined as

$$\frac{1}{E'} = 0.5 \left(\frac{1-\nu_1^2}{E_1} + \frac{1-\nu_2^2}{E_2} \right) \quad (3)$$

where ν_1 and E_1 are Poisson's ratio and the elastic modulus respectively of the head and ν_2 and E_2 are the Poisson's ratio and the elastic modulus respectively of the cup.

The contact radius of compliant layer joints cannot be explained by simple Hertzian contact theory. The contact radius needs to be determined using the equation below [28]

$$a = 0.94h_t^{0.38} \left(\frac{LR_x}{E_2} \right)^{0.21} \quad (4)$$

where h_t is the compliant layer thickness.

Coomassie engineering blue was used to determine the contact area experimentally. For the femoral heads against an UHMWPE cup, a computer-controlled Hounsfield testing machine was used to apply loads of 2000 N through a 15.88 mm radius stainless steel ball (which acted as the femoral head). A thin layer of blue was applied to the ball and it was loaded at 0.02 mm/s into the acetabular cup.

For the metal-on-polyurethane joints the Lloyd 6000R tensile testing machine was used to load a ball of 15.88 mm radius into the metal-backed polyurethane cups. An increased loading rate of 0.08 mm/s was used (to take account of the increased penetration). Three samples each of Tecoflex 85A, Tecoflex 93A, and Pellethane 80A were investigated. The internal radius of the cups was nominally 16.13 mm (± 0.01 mm), giving a radial clearance of 0.25 ± 0.05 mm. The cups were soaked for 24 hours in Ringer's solution prior to testing and the temperature-controlled cabinet was used during testing; this was maintained at 37 °C.

Figure 1 shows a typical acetabular cup stained region. Vernier callipers were used for both the con-

ventional UHMWPE cups and the polyurethane cups to measure the contact area (the stained region). This test was repeated three times with each cup and the dye was removed between each test with acetone.

A silicone moulding technique was also used to measure the contact radii of the UHMWPE and polyurethane cups. The femoral head was loaded into the acetabular cup with the curing silicone placed between them. This produced an annulus (the contact area) of silicone as the load was maintained to the completion of curing. Dow Corning silicone rubber was used with 1% (w/w) of curing agent to facilitate fast curing. The curing time was approximately 2 hours. The elastomer was placed in the base of the cup following coating of the prosthesis with mould release agent. The ball was then positioned in the cup and the assembly placed between the compression platens of the Lloyd 6000R tensile testing machine. A loading rate of 0.02 mm/s was used with the maximum load of 2000 N maintained for 6 hours to allow full curing of the silicone. The silicone moulding (see Fig. 2) was then removed and the central hole measured using Vernier callipers.

3.2 Lubrication analysis

Four biocompatible polyurethanes were used for tribological assessments, Estane 57 and 58, Tecoflex EG (80-100A), and Pellethane 80A. Conclusions of the work by Unsworth *et al.* [12] were that hardness values of 4–8 N/mm² produced the best tribological performance. Elastomers with hardness values in this range were used. An elastomer of a higher hardness was also used (Tecoflex 100A, which had a hardness of 9–10 N/mm²). Direct comparisons were made with UHMWPE cups with identical internal dimensions.

Frictional measurements of all the joints were carried out on Durham friction simulator II. The simulator works in a similar way to the Durham hip function simulator that has been described in detail elsewhere [7]. A dynamic loading cycle to simulate walking, similar to that found by English and Kilvington [29], was applied to the joints. The loading cycle had the maximum and minimum loads set at 2000 and 20 N respectively. Oscillatory motion was applied to the femoral head in the flexion/extension plane ($\pm 24^\circ$). The period of motion of each cycle was 1.2 s. The acetabular cup was positioned in a low-friction carriage and the femoral head was fixed into an upper moving frame; the prosthesis was therefore inverted relative to its position *in vivo*. The acetabular carriage was supported by externally

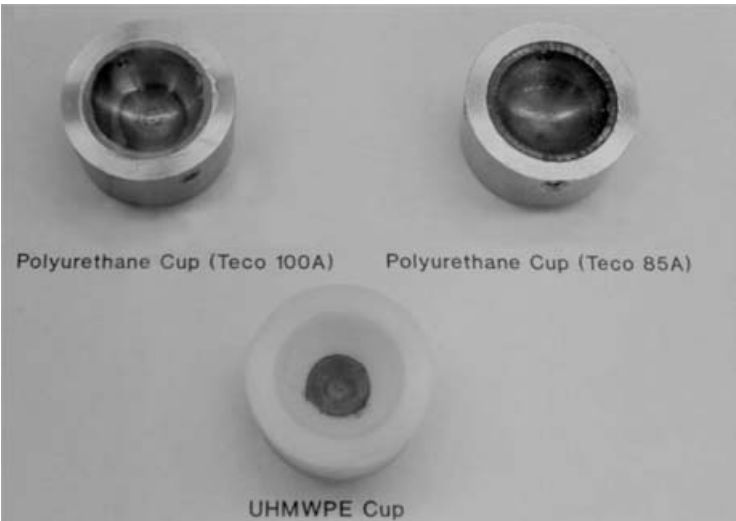


Fig. 1 Typical dyed regions from the loaded prosthetic device



Fig. 2 Typical silicone moulding from the loaded prosthetic device

pressurized bearings, which provided both a self-centring mechanism and a very low friction axis about which the carriage could rotate due to the frictional torque generated between the bearing surfaces. This rotation was resisted by a Kistler piezoelectric transducer, which was calibrated to measure torque.

The friction factor was measured and defined as [30]

$$f = \frac{T}{R_h L} \tag{5}$$

where T is the frictional torque between the bearing surfaces, R_h is the femoral head radius, and L is the axial load applied across the joint. Friction factor is similar to the coefficient of friction, but varies slightly depending on the elastic contact of the hip joint. The frictional torque, load, and angular displacement were measured throughout the loading cycle and an

average friction factor was taken from the high-load, high-velocity stage of the loading cycle (equivalent to the stance phase of walking).

Tests were performed with different viscosities of carboxymethyl cellulose (CMC) fluids ($0.001 < \eta < 0.150 \text{ Pa s}$ for the CoCrMo-on-Corethane joints and $0.005 < \eta < 0.065 \text{ Pa s}$ for the other joints). CMC fluids have been shown to have similar rheological properties to synovial fluid, i.e. they are shear-thinning [31]. All viscosities were measured on a Ferranti-Shirley cone-on-plate viscometer at a shear rate of 3000 s^{-1} at room temperature.

The mode of lubrication was determined by Stribeck analysis. In a Stribeck plot, the friction factor is plotted against Sommerfeld number, z , which is defined as

$$z = \frac{\eta u R_h}{L} \tag{6}$$

Here η is the viscosity of the lubricant and u is the entraining velocity of the bearing surfaces. A falling trend, i.e. a decrease in the friction factor with an increase in Sommerfeld number, together with friction factors greater than 0.01, is indicative of a mixed lubrication regime in which the load is carried in part by the contact between the asperities of the bearing surfaces and also by the pressure generated within the lubricant. An increase in friction factor with increasing Sommerfeld number and low values of friction factor (below 0.01) is indicative of a full fluid-film regime where the two surfaces are completely separated by the lubricant film and the frictional resistance is generated solely by the shear within the fluid.

3.3 Ovine arthroplasty model design

An ovine-based pre-clinical trial of compliant layer acetabular cups was to be conducted and the size and design of the component was therefore investigated. The three designs are detailed in Table 3. The film thicknesses expected from these three designs with various radial clearances were calculated using two different theories and then compared.

Firstly, the theory of Dowson and Yao [32] was used

$$h_{\min} = 1.59R_x \left(\frac{\eta u}{E''R_x} \right)^{0.56} \left(\frac{h_t E''}{E'''R_x} \right)^{0.36} \left(\frac{L}{E''R_x^2} \right)^{-0.20} \quad (7)$$

The constrained column model was used to derive the above formula. This model is restricted to compliant layer materials with a Poisson's ratio of less than 0.4, whereas the polyurethanes used as the compliant layer have a Poisson's ratio approaching 0.5. In order to take account of this, Dowson *et al.* [28] indicated that an adjusted modulus, E_{adj} , should be used, thus allowing the film thickness equations based on the constrained column model to be applied to incompressible layers

$$E_{\text{adj}} = \frac{4LR_x h_t}{\pi a^4} \left[\frac{(1+\nu_2)(1-2\nu_2)}{1-\nu_2} \right] \quad (8)$$

The modulus terms E'' and E''' are given by

$$\frac{1}{E''} = \frac{1-\nu_2^2}{E_{\text{adj}}} \quad (9)$$

$$\frac{1}{E'''} = \frac{(1+\nu_2)(1-2\nu_2)}{(1-\nu_2)E_{\text{adj}}} \quad (10)$$

where $\nu_2 = 0.4$ throughout. Secondly, the theory by Yao *et al.* [33] was used

$$h_{\min} = 6.46 \frac{h_t^{0.670} (\eta u)^{0.660} R_x^{0.543}}{E_2^{0.223} L^{0.437}} \quad (11)$$

4 RESULTS

4.1 Contact area analysis

The calculated contact radii for a conventional metal/UHMWPE prosthesis, a compliant layer pros-

thesis, and a natural joint are 10.9, 14.9, and 9.3–19.6 mm respectively. The UHMWPE cups were used to confirm the accuracy of the dye and moulding technique in experimentally assessing the contact radius. The dye method was found to produce a contact radius of 11.3 mm and the silicone moulding technique gave a contact radius of 12.4 mm. A good correlation was noted between the experimental measurement technique and the calculations.

The experimental methods that provided accurate correlation with theory for UHMWPE cups were investigated for the compliant layers to determine the contact region of the joints. The results are shown in Fig. 3 (this is a simplified version of the previously published figure [34]). Values of penetration for the polyurethane layers ranged from 0.25 to 0.35 mm. This was determined from the increase in displacement from a holding load of 200 N to a maximum load of 2000 N. Over this range of penetrations, contact radii were about 16–18 mm. Values of the contact radii obtained from the silicone moulding and dye transfer techniques are 15.5–17.5 mm and 14.5–16.3 mm respectively. Both the silicone mouldings and dye transfer techniques agree well with the penetration studies. The calculated value of contact radius also agrees well.

4.2 Lubrication analysis

Friction tests were carried out on each of the compliant layer joints and therefore Stribeck plots were

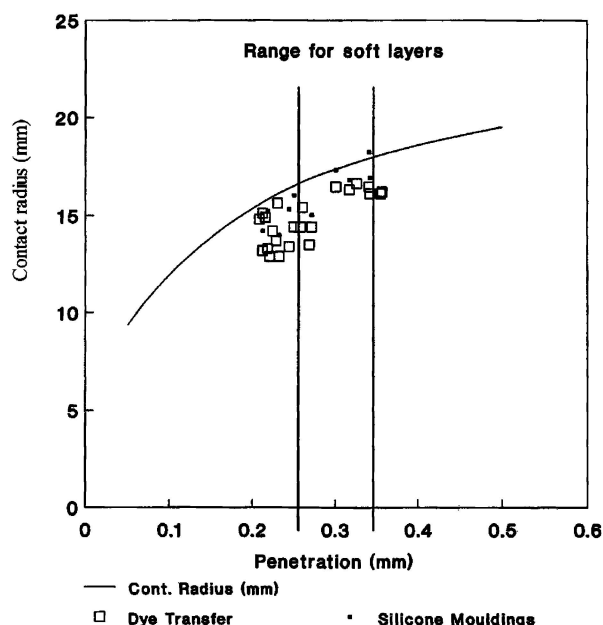


Fig. 3 Geometric calculations of contact radii for soft layer joints from penetration studies, with the experimental results of dye transfer and silicone moulding [34]

Table 3 Design parameters of the prototype ovine arthroplasty model

Design parameter (mm)	Case 1	Case 2	Case 3
Acetabular cup outside diameter	29	26	26
Layer thickness	2	2	1
Head diameter	22.23	16	18

produced. The Stribeck plots are shown in Fig. 4, except for the Corethane compliant layer joint, which is shown in Fig. 5 [35]. Aside from layers of Tecoflex 100A, they all showed very low friction factors with a rising trend as the lubricant viscosity was increased. This suggests that full fluid-film lubrication was present throughout the range of lubricant viscosities giving friction factors of 0.01 and under for each of the biocompatible elastomers apart from Tecoflex 100A. Tecoflex 100A showed a Stribeck plot that moved from mixed lubrication at the lower viscosity lubricants to full fluid-film lubrication at the higher viscosity lubricants. A metal-on-UHMWPE joint was also tested (see Fig. 6). This showed much higher friction and a falling Stribeck curve, indicative of mixed lubrication. Friction factors in the region of 0.02–0.04 were produced.

4.3 Ovine arthroplasty model design

The results of the theoretical calculations of film thickness for the various proposed ovine arthroplasty model designs are shown in Figs 7 and 8. Both the equations used to calculate the minimum film thickness gave very similar values. The results illustrate the effects of head radius and layer thickness on the

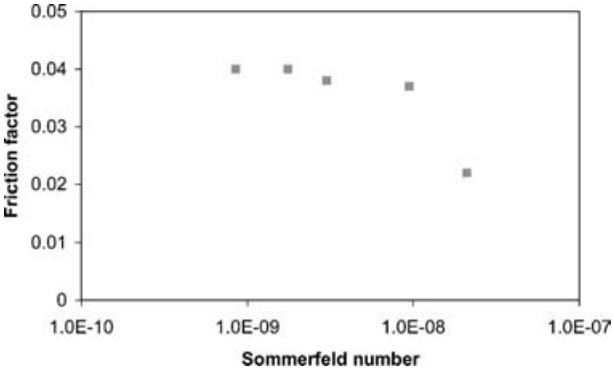


Fig. 6 Stribeck plot for the stainless steel/UHMWPE joint

minimum film thickness. The largest head diameter and layer thickness (case 1) gives the highest film thickness. Case 2 gives higher results compared with case 3, illustrating the greater importance of layer thickness compared with head diameter. Corethane was chosen as the best material to use for the ovine arthroplasty model as this is a bio-stable polycarbonate urethane that has performed well in friction studies [35].

5 DISCUSSION

The UHMWPE cups gave similar results for the calculated contact radius and the experimentally determined contact radius using both the silicone moulding technique and the dye transfer technique. Therefore, Hertzian contact theory agreed well with the experimental measurements for the conventional metal-on-UHMWPE joints.

The dye transfer technique produced excellent correlation with the theoretical calculations for the polyurethane joint. The silicone moulding technique also showed reasonable correlation with the other two techniques, although polyurethanes show a degree of viscoelastic behaviour which can result in creep and material flow away from the contact region. With the loading applied for up to six hours to allow full curing of the silicone, creep could lead to increases in the area of contact.

The Stribeck plots for the compliant layer joints show that for hardnesses of less than 6 N/mm² these joints operate within the full fluid-film lubrication regime. The values of friction factor are similar to those found previously [12, 36, 37]. Full fluid-film lubrication will result in a reduction in the production of wear particle formation by eliminating asperity contact. This lubrication may be affected by the possible surface damage caused by third body

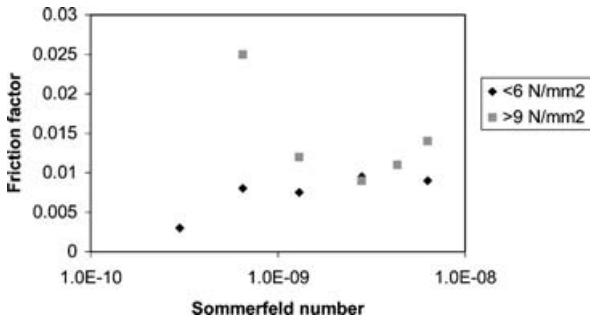


Fig. 4 Stribeck plot for soft layer joints of hardness <6 N/mm² and a soft layer joint of hardness >9 N/mm²

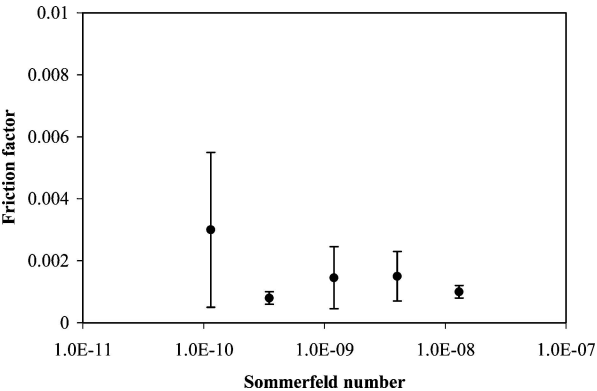


Fig. 5 Stribeck plot for a polyurethane (Corethane) compliant layer joint [35]

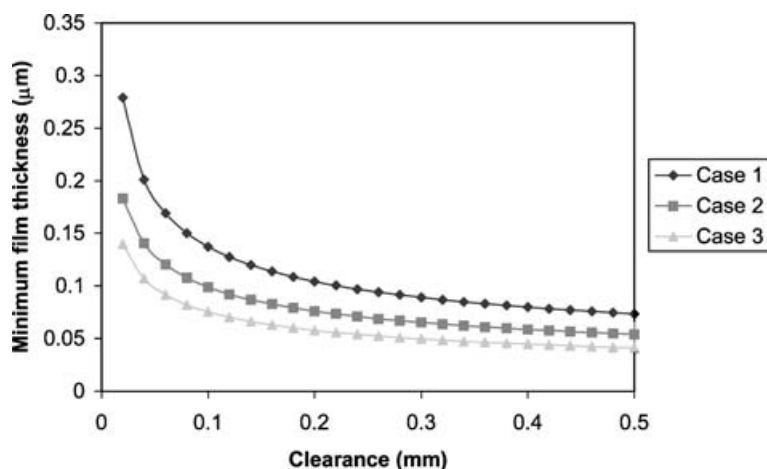


Fig. 7 Theoretical film thickness for the prototype ovine cups [32]

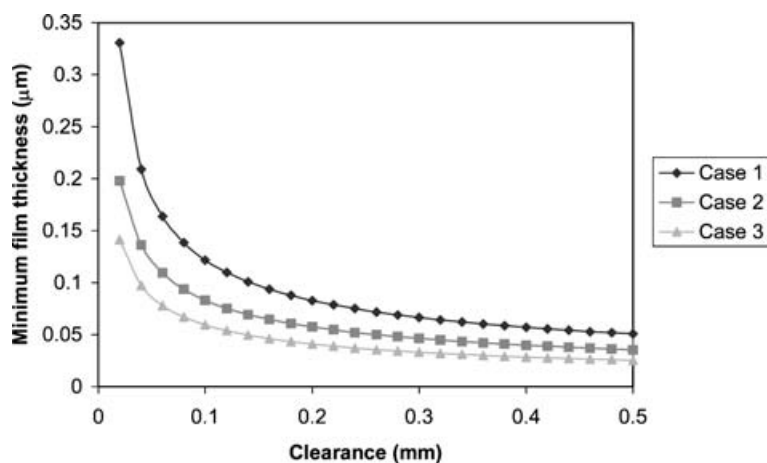


Fig. 8 Theoretical film thickness for the prototype ovine cups [33]

particles such as bone cement debris. The effect of bone cement particles on the friction of these bearing surfaces has recently been reported [38]. Also, start-up friction may be deduced to be a concern [39, 40]. However, both these features have been shown to create little by way of concern. The squeeze-film lubrication that is produced in these compliant layer joints actually improves the maintenance of the fluid film, which remains present for a longer period of time than it would do for hard bearing surfaces or conventional joints. If left for a long enough period for this fluid film to be depleted, tests have shown that the higher start-up friction lasts only for approximately 0.4 s of the first walking cycle. This will be the subject of a future publication. This future publication also discusses the manufacturing tolerances within these compliant layer acetabular cups. Briefly, due to the incompressible nature of this material, it is essential that the radial clearance is above 0.08 mm to prevent the acetabulum from grabbing the femoral component. Provided

it is greater than this, then reasonable clearance has little effect on the friction.

The theoretical analysis of the minimum film thickness developed between the bearing surfaces in the ovine arthroplasty model designs showed that the compliant layer thickness was of particular importance. In addition to this, the head diameter was of significance. However, as case 2 gave larger minimum film thicknesses than case 3, the layer thickness was shown to be of greater importance than the head diameter. Given the total size constraint of 26 mm outside diameter for the ovine acetabular cup, case 2 would be the best design for this prosthesis. Both of the equations for the minimum film thickness gave very similar values.

6 CONCLUSIONS

The theoretical calculations for the contact radii were close to the experimentally determined values for

both the UHMWPE joints and the PU joints. The friction factors of four biocompatible polyurethane materials were investigated. Low friction was produced by all the joints with a hardness of 6 N/mm² and less. These friction factors were significantly lower than the conventional metal-on-UHMWPE joints. However, the higher hardness material (9–10 N/mm²) gave slightly higher friction factors. A layer thickness of 2 mm was found theoretically to be the best thickness for the design of the ovine arthroplasty model. With further optimization, clinical trials should show that these joints operate with reduced wear rates.

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APPENDIX

Notation

a	contact radius
BD	1,4-butandiol
E'	equivalent elastic modulus
E_1	elastic modulus of the femoral head
E_2	elastic modulus of the acetabular cup
f	friction factor
HMDI	4,4'-methylene biscyclohexane diisocyanate (or hydrogenated 4,4'-diphenylmethane diisocyanate)
HMEC	poly(1-6-hexyl 1,2-diethyl carbonate) diol
h_t	layer thickness
L	applied load
MDI	4,4'-diphenylmethane diisocyanate
PTMEG	polytetramethylene ether glycol (also abbreviated to PTMO or PTMG)
R_c	radius of the acetabular cup
R_h	radius of the femoral head
R_x	equivalent radius
T	frictional torque
u	entraining velocity = $(u_1 + u_2)/2$
u_1	sliding velocity of the femoral head
u_2	sliding velocity of the acetabular cup
z	Sommerfeld number
η	lubricant viscosity
ν_1	Poisson's ratio of the femoral head
ν_2	Poisson's ratio of the acetabular cup